DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

709

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-09

November 18, 1997

Charles E. Williams, M.D.
Aloma Winter Park Medical Ctr.
3027 Aloma Avenue
Winter Park, Florida 32792

Dear Dr. Williams:

Your facility was inspected on August 19, 1997 by a representative of the State of Florida, State Department of Health and Rehabilitative Services, Bureau of Radiation Control, under contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

- Records indicate that there was no medical physicist survey done for the x-ray system: [redacted]; Mammo

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection.

In addition, the following Level 2 noncompliances were listed on the inspection report provided to you at the close of the inspection. These level 2 noncompliances include:

- Interpreting physicians, [redacted], do not meet the continuing experience requirement, i.e., interpreting an average of 40 patient examinations per month over 24 months.

On August 18, 1997 you responded by letter to the Level one noncompliances found during this inspection. On September 19, 1997 you responded to the level one and level two non compliances but did not include documentation for the level two noncompliances. On November 14, 1997 at the request of the Regional Radiological Health Representative, R. Thomas Trout, you faxed the documentation

for the level two noncompliances. From this information we determined that your response appears to be adequate. These corrective actions will also be evaluated during the next inspection. We appreciate your swift action in making these corrections to provide your patients with quality mammograms.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 and regulations under the Act. The specific deficiencies noted in the letter and in the printed summary of test results listed under the Level 1 and 2 headings on your MQSA Facility Inspection Report, issued at the close of the inspection, may be symptomatic of serious underlying problems in your facility's quality assurance program for mammography.

If you had not taken prompt action to correct these violations, it may have resulted in regulatory action being initiated by the Food and Drug Administration without further notice. A facility may be subject to civil money penalties up to $10,000 for each failure to substantially comply with, or each day on which a facility fails to substantially comply with the Standards. A facility may also have its certificate suspended or revoked for failure to comply with the Standards. Continuation or any activity related to the provision of mammography by a facility that constitutes a serious risk to human health may result in injunction.

You should be advised that FDA regulations do not preclude enforcement of requirements under State laws and regulations. In some cases, State requirements may be more stringent than requirements under FDA regulation. You may receive a letter or notification from the State advising you of this fact. When conducting corrective actions, you should take into consideration the more stringent State requirements. A copy of your response to the FDA should always be sent to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Thomas Trout, FDA, Southeast Regional Radiological Health Representative, at (404) 347-3576.

Sincerely yours,

Edward R. Atkins

Edward R. Atkins
Acting Director
Florida District